UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE PHILIP MORRIS INTERNATIONAL INC. SECURITIES LITIGATION	18 Civ. 8049 (RA) **ORAL ARGUMENT REQUESTED**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT

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Defendants Philip Morris International Inc. ("PMI"), André Calantzopoulos, Martin G. King, Jacek Olczak, Manuel C. Peitsch, Frank Lüdicke and Patrick Picavet (the "Individual Defendants" and, together with PMI, "Defendants") submit this memorandum of law in support of their motion to dismiss the Consolidated Amended Complaint ("CAC") (Ex. 1, cited as "¶ _").[1]

PRELIMINARY STATEMENT

The claims in the CAC are based on (i) debunked criticisms of clinical studies that were fully disclosed to the FDA and the public and (ii) unanticipated slowing sales growth in one PMI market (Japan), which Defendants promptly disclosed to investors. Neither of these theories can support a claim for securities fraud under Section 10(b). Accordingly, the CAC should be dismissed.

Plaintiffs' claims relate to an innovative PMI tobacco product called IQOS, which is designed to switch smokers who would otherwise continue to smoke to a better alternative to cigarettes. Unlike cigarettes, which burn tobacco, IQOS heats tobacco, without combustion, fire, ash, or smoke.[2] As a result, IQOS reduces the levels of harmful and potentially harmful constituents ("HPHCs") by an average of more than 90% versus cigarettes. PMI's development and commercialization of IQOS beginning in 2014 is part of the Company's well-publicized mission over the past several years to develop better alternatives to cigarettes for adult smokers, with the goal of a smoke-free future. PMI first launched IQOS in limited test markets in Japan in

[1] Unless otherwise indicated, internal citations and quotations are omitted, emphasis is added, and "Ex. __" refers to exhibits attached to the Declaration of Kevin M. McDonough. The Court may consider documents incorporated into the CAC by reference, SEC filings, and "information already in the public domain and facts known or reasonably available to the shareholders." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 539 n.13 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

[2] To use IQOS, a consumer inserts a consumable tobacco unit (called HEETS or HeatSticks) into the IQOS holder, which contains an electronically controlled heater. PMI, *IQOS: Tobacco Meets Technology*, https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system.

2014 and then launched it on a larger scale in 2016, in markets outside of the United States, to impressive commercial success. IQOS is the world's leading smoke-free inhalable alternative tobacco product for those who would otherwise have continued smoking. It is available in more than 45 countries, and PMI estimates that more than 7 million adult smokers have stopped smoking and switched to IQOS. IQOS sales accounted for approximately $739 million, or 1.0%, of PMI's net revenue in 2016, and approximately $3.793 billion, or 4.9%, of PMI's net revenue in 2017.[3]

PMI sought to bring this successful product to the U.S. by applying for authorization from the U.S. Food and Drug Administration ("FDA"). In that connection, PMI conducted and *disclosed* numerous clinical and non-clinical studies on IQOS, and submitted over two million pages of scientific data to the FDA in support of the Company's applications to (i) sell IQOS in the U.S.; (ii) market it as a reduced-risk tobacco product; and (iii) market it as a reduced-exposure product. While those applications were pending, in December 2017, *Reuters* published an article alleging "irregularities" in certain IQOS clinical trials. *Reuters* made clear that it "did not find any evidence that the outcome of the experiments presented by the company to the FDA was manipulated or falsified," but nonetheless provided its "findings" to the FDA. Ex. 12, *Reuters* Article, at 2.

In a widely-publicized development that Plaintiffs omitted from the CAC, on April 30, 2019, the FDA authorized the sale of IQOS in the U.S. The FDA's decision—which followed a lengthy, "rigorous science-based review" of PMI's application—announced that IQOS was "appropriate for the protection of public health" because it "produce[s] fewer or lower levels of

[3] PMI has clearly articulated its objectives in driving toward a smoke-free future: "If you don't smoke, don't start. If you smoke, quit. If you don't quit, change." *See* www.pmi.com/itstime/it's-time-to-unsmoke---why-now. Since 2008, PMI has invested over $6 billion in research and development of smoke-free products, working with external laboratories and qualified Clinical Research Organizations around the world. *See* www.pmi.com/science-and-innovation.

some toxins than combustible cigarettes." Ex. 2, FDA Release (Apr. 30, 2019), at 1. IQOS is the only inhalable, smoke-free alternative to cigarettes the FDA has authorized for sale since Congress gave it jurisdiction over tobacco products pursuant to the 2009 Family Smoking Prevention and Tobacco Control Act. The FDA has not yet announced a decision on PMI's separate application for authorization to market IQOS with specific reduced-risk or reduced-exposure messages.

While PMI was seeking regulatory authorization in the U.S., IQOS grew in popularity in other markets—most notably Japan—where, unlike in the U.S., no pre-market authorization is required. Throughout 2017, IQOS' quarterly market share in Japan grew at an unprecedented pace, resulting in supply shortages and restrictions on sales. After securing a second supplier in late 2017 to ease supply constraints, PMI anticipated that IQOS sales in Japan would continue to grow, and it shared those expectations with investors. But the rate of IQOS growth in Japan slowed down earlier than projected, which PMI promptly disclosed in its April 2018 first quarter earnings report—even before the slower-than-expected growth had an impact on PMI's financial performance, and despite the fact that PMI remained on track to double its global sales of IQOS.

When Plaintiffs' allegations—that Defendants fraudulently concealed material defects in IQOS clinical trials and purposefully overstated IQOS' growth prospects in Japan—are considered in light of these undisputed facts, it is clear that Plaintiffs have not adequately pleaded that any of the statements in the CAC were materially false or misleading, and in any event, Plaintiffs have not come close to pleading the required strong inference of scienter.

First, Plaintiffs fail to plead an actionable misstatement or omission. The vast majority of the statements Plaintiffs challenge regarding IQOS clinical trials and its projected performance in Japan are inactionable opinions, forward-looking statements, and/or statements of corporate optimism. To the extent that Plaintiffs challenge any factual statements made by Defendants, the CAC offers no support for and often directly contradicts Plaintiffs' speculative theory of falsity.

Second, Plaintiffs' claims are deficient for the independent reason that Plaintiffs do not allege particularized facts to support a compelling inference that Defendants acted with scienter. The CAC relies on routine stock sales by one Individual Defendant and two non-defendants, but none of that trading activity is noteworthy given that the trades are entirely consistent with the individuals' regular trading history and they each retained far larger quantities of stock than they sold—critical facts that Plaintiffs entirely ignore. Unable to show motive and opportunity, the CAC also lacks any cognizable allegations that any Defendant was reckless. Moreover, Plaintiffs ignore critical facts defeating any inference of scienter—that (i) *Reuters* did not find evidence that PMI falsified its publicly disclosed data, (ii) the FDA authorized the sale of IQOS following a "rigorous scientific review" of the millions of pages of data that PMI provided, and (iii) PMI senior management retained substantial amounts of PMI shares throughout the Class Period.

These pleading deficiencies cannot be cured and, accordingly, the CAC should be dismissed with prejudice.

FACTUAL BACKGROUND

A. PMI & The Individual Defendants

PMI is a publicly traded Virginia holding company with subsidiaries and affiliates engaged in the manufacture and sale of cigarettes, other tobacco products and other nicotine-containing products in markets outside of the U.S. ¶¶ 2, 22. The Individual Defendants are current executives or senior management of PMI.[4] ¶¶ 23-28. As relevant here, PMI is committed to the development and commercialization of smoke-free alternatives to cigarettes known as reduced-risk products

[4] Mr. Calantzopoulos served as PMI's CEO at all times relevant to the CAC. Mr. King became CFO in January 2018. Mr. Olczak has been COO since January 2018, and prior to that, served as the CFO. During the Class Period, Prof. Peitsch served as Chief Scientific Officer for RRPs and Dr. Lüdicke served as Chief Medical Officer. Dr. Picavet became Director of Medical Affairs in February 2017, after serving as the Director of Clinical Assessment. ¶¶ 23-28.

("RRPs")—*i.e.*, products that present, are likely to present, or have the potential to present, less risk of harm to smokers than continuing to smoke cigarettes. ¶¶ 3-4. PMI's leading RRP brand, IQOS, is an electronic device that heats specially designed tobacco units at a precise temperature that does not create combustion but instead generates a primarily water-based aerosol containing significantly lower quantities of HPHCs than found in cigarette smoke. ¶¶ 3, 35-36. Following an initial limited commercial launch in Japan in 2014, IQOS is now sold in dozens of countries. ¶ 5; Ex. 9, CAGNY Pres., at 40. As discussed below, on April 30, 2019—over one week before Plaintiffs filed the CAC—the FDA authorized PMI's application to sell IQOS in the U.S.

B. PMI's Regulatory Applications To Sell IQOS In The U.S.

In December 2016, PMI submitted an application to the FDA for IQOS to be deemed a modified risk tobacco product ("MRTP" or, when referring to the application, "MRTPA"), ¶ 5, and in March 2017, PMI submitted a Premarket Tobacco Product Application ("PMTA"), which sought authorization to market IQOS more generally, *i.e.*, not as an MRTP, Ex. 4, PMI Press Release (Mar. 31, 2017). In creating the MRTP designation, Congress sought to encourage the development of better alternatives to cigarettes. ¶ 42. For the FDA to classify a tobacco product as an MRTP, an applicant must provide scientific evidence that the product will (i) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (ii) benefit the health of the population as a whole. ¶ 47; Ex. 14, TPSAC Tr. (Jan. 24, 2018), at 17.

PMI submitted more than two million pages of data and materials to the FDA in support of the MRTPA, including evidence from eight clinical studies of IQOS performed by third party Clinical Research Organizations. Ex. 13, *Bloomberg* Article (Oct. 6, 2016), at 5; ¶ 51. Four studies assessed whether IQOS could realistically serve as an alternative to traditional cigarettes. Ex. 7, MRTPA Exec. Summ., at 159-60. The studies measured 62 participants' nicotine absorption over 24 hours following a single use of IQOS, Ex. 8, PMI, "The Science Behind the Tobacco

Heating System" (Oct. 2, 2017), at 10, and generally found that IQOS was likely to be adopted as a viable replacement for cigarettes by current smokers, based both on subjective preferences and nicotine intake, Ex. 7, MRTPA Exec. Summ., at 160. At the same time, most of the studies demonstrated that total tobacco consumption actually *decreased* in those smokers who completely switched to IQOS. *Id*.

PMI conducted four other studies to assess whether IQOS reduces exposure to harmful chemicals versus smoking, and whether any such reductions correlated with favorable changes in clinical risk endpoints—PMI's proxy for consumer health risks. *Id.* at 74. 160 smokers participated in each study, which involved five days of confined IQOS usage compared to (i) using cigarettes and (ii) abstaining from them. Ex. 8, PMI, "The Science Behind the Tobacco Heating System," at 10-11. For two of the studies, the five days of confined use were followed by 85 days of non-confined IQOS use to assess whether any initial reduction would be sustained for a longer period in a near real-world setting. Ex. 7, MRTPA Exec. Summ., at 74-75. All four studies found that after the confined usage, IQOS users had decreased levels of exposure to the measured dangerous chemicals, in some cases approaching reductions realized by those who ceased smoking entirely, and the longer duration studies showed similar results. *Id*. at 78, 81.

Throughout 2016 and 2017, the Company made the study protocols and results available for public review, published over 100 peer-reviewed articles in leading scientific journals and amended its FDA application multiple times to provide additional study results and other information. ¶¶ 32, 51, 53, 85; Ex. 18, CAGNY Tr. (Feb. 21, 2018), at 5. In 2018, PMI went so far as to publicize the studies' raw data and invite independent studies of its IQOS product. Ex. 18, CAGNY Tr. (Feb. 21, 2018), at 5. From the very beginning of the Class Period, PMI also summarized the salient features of its clinical studies (including the duration of the studies) and the results in its periodic SEC filings and other public sources. *E.g.*, ¶ 159. While PMI viewed

the studies' results favorably, *see, e.g.*, ¶ 159, it expressed clear and unambiguous caution in its public disclosures, before and during the Class Period, regarding the prospect of regulation permitting the sale of RRPs with reduced-exposure or reduced-risk claims:

> As we work to develop evidence to substantiate the risk reduction potential of our products, we will review our ability to make claims of reduced exposure or risk based on applicable laws and regulations and, as we are already doing, engage with regulators and share the evidence with them. We are also engaging with the scientific community, sharing our assessment approach and the results we have generated. *There can be no assurance that we will succeed in our efforts or that regulators will permit the marketing of our RRPs with substantiated claims of reduced exposure or risk as compared with smoking cigarettes*.

Ex. 11, Q1 2016 10-Q, at 46; *e.g.*, *id.* at 66; *see also* ¶ 273.

The FDA formally accepted for consideration PMI's MRTPA and PMTA on May 2017 and August 2017, respectively (¶ 45; Ex. 3, 2017 10-K, at 34), eventually referring the MRTPA to its Tobacco Products Scientific Advisory Committee ("TPSAC") for review. ¶ 95; Ex. 14, TPSAC Tr. (Jan. 24, 2018), at 10-17. While these applications were pending, in December 2017, *Reuters* published an article alleging irregularities in PMI's clinical studies. Ex. 12, Tom Lasseter, et al., "Scientists Describe Problems in Philip Morris E-Cigarette Experiments," *Reuters* (Dec. 20, 2017) ("*Reuters* Article").

But consistent with PMI's public statements regarding its compliance with Good Clinical Practices ("GCP"), *Reuters* acknowledged that PMI halted a noncompliant study at a laboratory in Japan, and that PMI similarly terminated studies where other procedural failures occurred. *Id.* Moreover, the reporting "did not find any evidence that the outcome of the experiments presented by the company to the FDA was manipulated or falsified." *Id.* Although *Reuters* provided its findings to the FDA for its consideration in late 2017, *id.*, PMI had already been transparent with the FDA about the subject studies, ¶¶ 32, 53, and, to date, the agency has not raised any question

with the Company about these clinical studies, *see generally* Exs. 14, 16, TPSAC Trs. (Jan. 24-25, 2018); Ex. 2, FDA Release (Apr. 30, 2019).

One month later, TPSAC conducted a two-day hearing regarding PMI's MRTPA, ¶ 99, for the purpose of making non-binding recommendations to the FDA as to whether PMI had provided sufficient evidence of three claims regarding IQOS:

1. "Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases."

2. "Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes."

3. "Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."

Ex. 14, TPSAC Tr. (Jan. 24, 2018), at 28-29. During the two-day hearing, TPSAC members engaged in robust scientific scrutiny, focusing on the evidence presented and breadth of the proposed product messages. *See* Exs. 14, 16, TPSAC Trs. (Jan. 24-25, 2018). In a non-binding vote at the end of the hearing, TPSAC voted overwhelmingly that switching completely from cigarettes to IQOS significantly reduces a smoker's exposure to HPHCs, while voting against recommending claims #1 and #2. Ex. 15, TPSAC Minutes (Jan. 24-25, 2018). Although it had the *Reuters* findings, TPSAC made no reference to or findings of any purported irregularities in PMI's studies, nor did it find that PMI failed to follow GCP. *See* Exs. 14, 16, TPSAC Trs. (Jan. 24-25, 2018).

In April 2019, with PMI's MRTPA still pending, the FDA granted the Company's PMTA for IQOS, announcing that it had conducted "a rigorous science-based review" of the product and "determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes." Ex. 2, FDA Release (Apr. 30, 2019), at

1. The FDA's basis for authorizing the sale of IQOS in the U.S. aligned with claim #3 from PMI's MRTPA, seeking authorization to market IQOS as a reduced exposure product: "[T]he aerosol produced by the IQOS [ ] contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke . . ." *Id.* at 2. To date, however, the FDA has not reached a final conclusion on PMI's MRTPA.

C. The Success Of IQOS In Japan & PMI's Expectations For 2018

PMI first launched IQOS in Japan on a limited scale in 2014, followed by a nationwide rollout in April 2016. ¶¶ 38, 107. Over the four quarters of 2017, IQOS gained increasing market share, growing from 7.1% to 10.0% to 11.9% to 13.9%, despite supply constraints in Japan. Ex. 9, CAGNY Pres., at 42; Ex. 3, 2017 10-K, at 24. In 2016 and 2017, IQOS sales accounted for approximately 1.0% and 4.9%, respectively, of PMI's net revenue. Ex. 3, 2017 10-K, at 25-26.

When PMI announced its fiscal year 2017 earnings on February 8, 2018, Mr. Calantzopoulos expressed optimism about IQOS in general and the Japan market specifically, stating that the Company "expect[ed]" IQOS in Japan "to grow further in the first quarter [of 2018] following a planned lifting of the restriction on IQOS device sales;"[5] "[c]ontinued investment behind IQOS in 2018 [was] expected to further drive its positive momentum;" and that PMI was "begin[ning] 2018 in excellent shape." Ex. 19, Earnings Call Tr. (Feb. 8, 2018), at 6-7; Ex. 20, 2017 Earnings Release (Feb. 8, 2018), at 3; *see also* ¶¶ 276, 278, 280. On February 21, 2018, Messrs. Calantzopoulos, Olczak and King made a presentation to the Consumer Analyst Group of New York ("CAGNY"), during which Mr. Olczak noted that IQOS' market share in Japan,

[5] In mid-2016, demand for IQOS heated tobacco units in Japan outpaced what PMI could supply to the market, leading PMI to institute a cap on the number of devices available for sale. *See* Ex. 29, Earnings Call Tr. (Feb. 2, 2017), at 5. After increasing its manufacturing capacity for heated tobacco units and securing a second supplier of IQOS devices in late 2017, PMI lifted the cap, enabling Japan retailers to carry and sell more devices. Ex. 3, 2017 10-K, at 33.

measured in terms of retail "offtake share," had risen from 13.9% in the fourth quarter of 2017 to 16.3% by the end of January 2018. Ex. 9, CAGNY Pres. at 42; Ex. 18, CAGNY Tr. (Feb. 21, 2018), at 9.[6] He further noted that IQOS was being sold in 38 markets, and had recorded sequential growth in heated tobacco unit market shares through January 2018, with impressive performances in Korea, Portugal and Romania. Ex. 18, CAGNY Tr. (Feb. 21, 2018), at 9.

D. PMI Announces Q1 2018 Results

Two months later on April 19, 2018, PMI announced its first quarter 2018 earnings, reporting that it was increasing full-year earnings per share guidance, Ex. 5, Q1 2018 Earnings Pres. (Apr. 19, 2018), at 1, and that PMI had achieved quarter-over-quarter growth in IQOS' market share in Japan, rising from 13.9% to 15.8%, Ex. 22, Earnings Call Tr. (Apr. 19, 2018), at 7. But based on the full first quarter 2018 IQOS sales data, PMI concluded that IQOS growth in Japan had begun to slow compared to the Company's expectations, and management proactively disclosed this conclusion to the market even though the financial impact would not occur until later in the year, if not reversed. *Id.* at 9 ("[W]e can project forward and see that our HeatSticks [the tobacco unit used in IQOS] sales, which come as a lagging indicator to the device sales, are likely to be a little bit slower than what we had flagged at the year-end call"); *id.* at 10.

Mr. King explained during the April 19 earnings call that, looking back, the slightly slower growth in Japan "was due to still limited awareness of IQOS' increased availability and, more importantly, to the fact that we are reaching, earlier in the year than we had anticipated, the more conservative consumers." *Id*. at 5. Asked why the quarter-end result differed from the monthly market share figure provided at the February CAGNY conference, Mr. King elaborated:

[6] PMI's presentation slides explained that "offtake share" was the "*estimated* retail offtake volume of heated tobacco units divided by the sum of *estimated* total offtake volume for cigarettes, heated tobacco units and, *where the data is available*, other RRPs." Ex. 9, CAGNY Pres., at 67.

> [W]e mentioned that we were *expecting* to be able to meet the additional HeatSticks units inventory that we had sent to Japan with additional devices from our second supplier that had ramped up production. And we did ship the additional devices, and we were *anticipating* a substantial surge because, as you know, we had short the market for quite some time. *And as it turned out*, we were closer to having met market demand than we realized. We [were] *anticipating* that we would reach some sort of a plateau later in the year, given that we knew the consumer dynamics that we had -- close to saturating the early adopters and innovators. It's just coming a bit earlier in the year than what we had *foreseen*.

Id. at 8. Mr. King explained that IQOS "continue[s] to grow in Japan," but the issue was simply the "speed of the growth." *Id.* at 13. At the same time, Mr. King highlighted that PMI remained "on track to double [its] worldwide in-market sales of heated tobacco units compared to 2017," *id.* at 6, and that the "growth of [its] RRP portfolio, coupled with the enduring strength of our combustible tobacco brands" drove "better than expected" first quarter results, *id.* at 7.

ARGUMENT

I. PLAINTIFFS FAIL ADEQUATELY TO PLEAD A SECTION 10(B) CLAIM

To assert a Section 10(b) claim, Plaintiffs must plead facts showing (i) a material misrepresentation or omission; (ii) scienter; (iii) a connection between the misrepresentation or omission and the purchase or sale of a security; (iv) reliance upon the misrepresentation or omission; (v) economic loss; and (vi) loss causation. *See Pac. Inv. Mgmt. Co. LLC v. Mayer Brown LLP*, 603 F.3d 144, 151 (2d Cir. 2010). In addition to the requirements under *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), that Plaintiffs allege "facts" establishing a "plausible" claim, Plaintiffs must also satisfy the heightened pleading requirements of both Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *See ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009).

The PSLRA requires that Plaintiffs (i) "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading"; and (ii) "with respect to

each [alleged] act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" (or scienter). 15 U.S.C. §§ 78u-4(b)(1), (2). The CAC fails to state a Section 10(b) claim for multiple, independent reasons, including that it does not allege with particularity that (i) statements by PMI or any Individual Defendant were false; or (ii) that any Defendant acted with fraudulent intent, *i.e.*, scienter.

A. Plaintiffs Fail Adequately To Plead A False Or Misleading Statement

Plaintiffs challenge nearly 60 statements related to IQOS clinical studies over a two-year period, and 10 statements regarding IQOS sales growth in Japan over a two-week period, on behalf of a putative class of investors that purchased PMI stock from July 26, 2016 to April 18, 2018 (the "Class Period"). *See* ¶¶ 155-308. But Plaintiffs "must do more" than allege statements were false or misleading, "they must demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). The CAC does not meet this basic requirement.[7]

1. Statements Regarding PMI's Studies Were Not False Or Misleading

Plaintiffs' allegations do not establish that Defendants' statements regarding its IQOS clinical studies were false or misleading. Nor can they. Defendants' statements of current or historical fact were true when made, and their opinions and statements of corporate optimism that the law terms "puffery" are all immune from liability under well-settled law.

a. *Defendants Made No False Statements Regarding The Results Of The IQOS Studies*

Relying heavily on the *Reuters* Article, Plaintiffs allege that Defendants' statements about the results of the IQOS studies were false and misleading because, according to Plaintiffs, the study results were not "meaningful" in light of alleged irregularities and other flaws in the studies,

[7] A table identifying the reasons why each challenged statement is not actionable is attached as Appendix A ("App'x A"). *See Fogel v. Wal-Mart de Mexico SAB de CV*, 2017 WL 751155, at *18 (S.D.N.Y. Feb. 27, 2017) (accepting appendices that serve as "organizational tools").

other IQOS studies yielded less favorable results, and the results of PMI's studies did not support a claim of reduced risk. *See, e.g.*, ¶¶ 159-60, 169-70, 177-82, 185-86, 190-91, 200-01, 204-07, 211-12, 214-29, 233-34, 238-41, 246-54, 264-67; App'x A. These allegations fail for multiple reasons.

First, as Plaintiffs admit, PMI publicly disclosed the methodology and results of *all* of its IQOS studies, ¶ 53, and as *Reuters* has admitted, none of that information was "manipulated or falsified," Ex. 12, *Reuters* Article. Plaintiffs nonetheless claim that Defendants' statements summarizing PMI's publicly disclosed study results were false, but they do not identify a single false factual statement by *any* Defendant. For example, Plaintiffs do not dispute that PMI, as it disclosed, conducted six studies with short-term durations, which showed "a substantial reduction in relevant biomarkers of exposure to [HPHCs] in adult consumers," ¶ 190; or that PMI conducted two studies with three-month durations in which it "observed reduction in all 15 biomarkers of exposure to corresponding HPHCs measured in those who switched to IQOS compared to those who continued to smoke cigarettes," *id.*; or that IQOS showed "on average" a "90-95%" reduction of the "harmful chemicals found in tobacco smoke," with reductions of "approximately 98%" for "carbon monoxide and nitrogen oxides," ¶ 214. These concededly true summaries of clinical results cannot be the basis for a fraud claim. *See In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004) (securities claims "may not rely on statements that are true").

Second, Defendants' subjective interpretations of their publicly disclosed clinical study results, *e.g.*, that the "*totality* of the evidence" shows IQOS "has the *potential* to reduce the risk of smoking-related diseases in adult smokers who switch to it completely," ¶ 169; *see also*, *e.g.*, ¶¶ 223, 238, are inactionable opinions. *See Sanofi*, 87 F. Supp. 3d at 543 ("Courts have repeatedly held publicly stated interpretations of the results of various clinical studies to be opinions."). As the Second Circuit has held, Plaintiffs cannot manufacture a false statement by quibbling with

Defendants' opinions regarding clinical study results, and that is especially true here because the study results were public. *See, e.g.*, *Sanofi*, 816 F.3d at 214 ("Plaintiffs' allegations regarding Defendants' stated opinion about the [ ] trial results are little more than a dispute about the proper interpretation of data, a dispute this Court rejected as a basis for liability[.]"); *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013) ("where a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement").[8]

Moreover, Plaintiffs do not satisfy the *Omnicare* standard for pleading falsity of opinions. They do not allege that any Defendant disbelieved his own opinion regarding the IQOS study results or included a false embedded fact within an opinion statement. *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015). Nor have Plaintiffs pleaded that Defendants omitted important facts about the basis for their opinions, which the U.S. Supreme Court has described as "no small task." *Id.* at 1332. Indeed, the basis for Defendants' interpretation was made *public*. Plaintiffs latch onto what they call the "four undisclosed studies"—claiming they undermined Defendants' interpretations of the IQOS data. ¶¶ 85-88. But Plaintiffs concede that those studies *were* disclosed to the FDA and the public. ¶ 86.[9]

Third, armed with all of the data from the IQOS studies, as well as the *Reuters* investigation on which Plaintiffs so heavily rely, the FDA *authorized* the sale of IQOS in the U.S. Indeed, contrary to Plaintiffs' allegation that PMI's studies were "insufficient to provide meaningful data," ¶ 160, the FDA concluded that those studies demonstrate that "the aerosol produced by [IQOS]

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[8] *See also Nguyen v. New Link Genetics Corp.*, 2019 WL 591556, at *4 (S.D.N.Y. Feb. 13, 2019) (interpretations clinical results are "essentially no different than opinions, given that reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions"); *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 594-96 (S.D.N.Y. 2016); *In re MELA Scis., Inc. Sec. Litig.*, 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012).

[9] To the extent Plaintiffs contend that PMI could or should have disclosed the studies sooner, the FDA has not taken that position (and Plaintiffs do not allege otherwise).

contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke" and the "marketing of [IQOS] would be appropriate for the protection of the public health." Ex. 2, FDA Release (Apr. 30, 2019), at 2.

Plaintiffs make much of the non-binding TPSAC recommendations not to allow IQOS to be marketed as a reduced risk product. ¶¶ 94-103. But TPSAC also voted that PMI demonstrated that "[s]cientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body's exposure to [HPHCs]," and the FDA authorized IQOS for sale in the U.S. Ex. 15, TPSAC Minutes (Jan. 24-25, 2018), at 6; Ex. 2, FDA Release (Apr. 30, 2019). In any event, even if the FDA ultimately accepts TPSAC's recommendation that PMI failed to demonstrate that IQOS' reduction of *exposure* necessarily reduces the *risk* of tobacco-related diseases, that would not render Defendants' subjective assessments false or misleading. *See QRX Pharma*, 197 F. Supp. 3d at 598; *see also Sanofi*, 816 F.3d at 214 ("Defendants' statements were not misleading simply because the FDA disagreed with Defendants' interpretation of the data[.]"). Indeed, Defendants never publicly stated—much less guaranteed—that the FDA would authorize PMI to market IQOS as a reduced-risk product. To the contrary, Defendants specifically warned investors that the FDA may have a different interpretation of PMI's clinical study data, ¶ 202, which reasonable investors understand in any event, *Sanofi*, 816 F.3d at 214.[10]

b. *Defendants Made No False Statements Regarding Their Methodology For Testing IQOS*

Plaintiffs further allege that Defendants' statements regarding the methodology for the IQOS trials were false and misleading. *See, e.g.*, ¶¶ 167-68, 173-76, 236-37, 240-41, 249-50, 255-

[10] Contrary to Plaintiffs' allegations, *e.g.*, ¶¶ 163-64, 202-03, 273-74, PMI's comprehensive risk disclosures did not conceal already-materialized risks regarding regulatory approval. Indeed, the FDA still has not issued a decision on the MRPTA, and its decision on the PMTA was *positive*. *See In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 760-61 (S.D.N.Y. 2018).

56, 259. In support, Plaintiffs recite the same allegations that appear in the *Reuters* Article—*e.g.*, that the clinical trials were too short in duration, and that the third-party investigators conducting the studies overseas were "unqualified" and allegedly used "invalid" or "tainted" urine samples in components of two of the studies. *See* ¶¶ 80-84; *see also*, *e.g.*, ¶ 237. Those allegations also fail.

First, Plaintiffs' criticisms of PMI's accurately disclosed clinical methodology cannot be the premise for a securities fraud claim. *See Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869, at *6 (S.D.N.Y. May 29, 2013) ("[T]he securities laws do not recognize a fraud claim premised on criticisms of a drug trial's methodology, so long as the methodology was not misleadingly described to investors."). Plaintiffs complain, for example, that Defendants failed to disclose that "the durations of the studies were insufficient to provide meaningful data." ¶ 237. But Plaintiffs acknowledge that Defendants completely and accurately disclosed the duration of such trials to the FDA and the public—and, of course, the FDA ultimately authorized the sale of IQOS based in part on those trials. *See* ¶ 51 (listing "Duration of Exposure" in studies); ¶ 190 (quoting 10-Q disclosure that six studies had a five-day duration and two others were three-month trials). Admittedly true statements about clinical trials do not become false merely because others may disagree with the methodology. *Davison v. Ventrus Biosciences, Inc.*, 2014 WL 1805242, at *7 (S.D.N.Y. May 5, 2014) (on "Section 10(b) claim, a court does not judge the methodology of a drug trial"); *In re Keryx Biopharmaceuticals, Inc. Sec. Litig.*, 2014 WL 585658, at *10 (S.D.N.Y. Feb. 14, 2014) (dismissing claim that defendant misstated studies due to "the extent of the methodological flaws").

Second, Plaintiffs' allegations that Defendants omitted material facts about "irregularities" in the IQOS studies likewise miss the mark. *Reuters* stated that it "outlined its findings about the iQOS trials to [the FDA]," Ex. 12, *Reuters* Article, at 6, but the FDA nonetheless has granted PMI's application to market IQOS in the U.S. in part on the basis of those trials, Ex. 2, FDA

Release (Apr. 30, 2019). There are no allegations in the CAC that the FDA took issue with Defendants' execution of the IQOS studies, and in any event, the securities laws do not require a company to disclose deficiencies in clinical trials—*even if such criticisms came directly from the FDA*. *See, e.g.*, *MELA Sciences*, 2012 WL 4466604, at *13-14 (rejecting complaint premised on FDA's feedback about "the clinical trial's numerous flaws"); *Fort Worth Employers' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 231 (S.D.N.Y. 2009) (no duty to disclose FDA feedback critical of the design of an ongoing study); *Sanofi*, 87 F. Supp. 3d at 541 (same); *accord Hoey v. Insmed Inc.*, 2018 WL 902266, at *9 (D.N.J. Feb. 15, 2018) (A "study's alleged flaws or shortcomings need not be disclosed to a reasonable investor").[11]

Third, Defendants' inherently subjective statements regarding compliance with GCP are inactionable opinion statements. *E.g.*, ¶¶ 173, 175, 236, 255; App'x A; *In re Lehman Bros. Sec. & ERISA Litig.*, 131 F. Supp. 3d 241, 251 (S.D.N.Y. 2015) (auditor's statement of compliance with generally accepted auditing standards "cannot properly be characterized as a statement of fact given the general and often inherently subjective nature of the standards"); *see also Fait v. Regions Fin. Corp.*, 655 F.3d 105, 113 (2d Cir. 2011) ("inherently subjective" assertions are opinions). And Plaintiffs' allegations about Defendants' opinions regarding GCP compliance do not satisfy *Omnicare*. 135 S. Ct. at 1327, 1332. There is not a single non-conclusory allegation in the CAC that Defendants disbelieved their opinions or provided false facts regarding compliance with GCP, *id.* at 1327, and in fact, the CAC *suggests the opposite*, *see* ¶ 72 (acknowledging that after learning of potential GCP violations, Defendants "halted the study at that location" and "discard[ed] the data as non-complian[t] with GCP"). Nor does the CAC satisfy *Omnicare*'s omission prong,

[11] In any event, the FDA's own inspection of two clinical sites in the U.S. confirmed that proper protocol was followed and that no deviations occurred that "would compromise data validity and integrity." Ex. 17, PMTA Dec. Summ., at 62.

which requires Plaintiffs to "identify particular (and material) facts going to the basis for the issuer's opinion" that were omitted. *Lopez v. CTPartners Exec. Search Inc.*, 173 F. Supp. 3d 12, 24 (S.D.N.Y. 2016). No such omitted facts are pleaded here. As described in more detail below, (*infra* § I.B.2.a), the CAC is nearly devoid of allegations that Defendants were even *aware of* any uncorrected problems with the IQOS trials. For these reasons, none of the statements about GCP compliance is actionable.

The same is true for statements that PMI's "assessment approach" and studies "reflect[ed] the rigorous evidentiary package contemplated in the FDA's" Draft Guidance. *E.g.*, ¶ 161, 240. The FDA accepted PMI's PMTA and MRTPA—and now has granted the PMTA—and it has made no findings that contradict PMI's statements about its adherence to FDA guidance. Moreover, even if the FDA had made such findings, that would not render false Defendants' statements of compliance, *MELA Sciences*, 2012 WL 4466604, at *13-14, which are inactionable opinions in any event, *see Omnicare*, 135 S. Ct. at 1327, 1332.

c. *Defendants' Puffery Statements Are Not Actionable*

Plaintiffs also challenge statements of corporate optimism, or what the law terms "puffery," regarding the IQOS studies. Such statements are inactionable because they "are too general to cause a reasonable investor to rely on them." *ECA*, 553 F.3d at 206. For example, the CAC challenges statements describing the IQOS studies and analyses as "*extensive and rigorous*," "*very advanced*," "*point[ing] in the right direction*," "*[giving] us confidence*," "*unique* in its completeness and transparency," and "draw[ing] upon a team of *world-class* scientists." ¶¶ 157, 165, 173, 177, 183, 188, 195, 198, 209, 216, 231, 236, 240, 243-44, 246-47, 251-54, 260-64, 268,

271. Each statement is quintessential and inactionable puffery. *Fialkov v. Alcobra Ltd.*, 2016 WL 1276455, at *4 (S.D.N.Y. Mar. 30, 2016) ("*rigorously*" conducted enrollments inactionable).[12]

d. *Plaintiffs Do Not Adequately Allege A Violation Of Item 503*

Plaintiffs allege that Defendants violated Item 503 by failing to disclose adverse clinical data. ¶¶ 307-08. The undisputed facts belie that claim. "Item 503 requires that a company provide under the caption 'Risk Factors' a discussion of the most significant factors that make the offering speculative or risky." *Ong v. Chipotle Mexican Grill, Inc.*, 2017 WL 933108, at *10 (S.D.N.Y. Mar. 8, 2017). Defendants' statements about the IQOS clinical trials were thorough, detailed and accurate, *see supra* § I.A.1, and Defendants supplied investors with detailed warnings of the exact risks Plaintiffs claim were concealed, *see, e.g.*, Ex. 3, 2017 10-K, at 9 ("We may be unsuccessful in our attempts to introduce reduced-risk products, and regulators may not permit the commercialization of these products or the communication of scientifically substantiated risk-reduction claims."); Ex. 6, Q3 2017 10-Q, at 80 (same). Thus, if Item 503 applies at all to the 10-K and 10-Q disclosures, Plaintiffs' allegations do not establish a violation. *See Chipotle*, 2017 WL 933108, at *17 (no Item 503 claim where "risk" and "potential impact" was "adequately described").[13]

[12] *Steinberg v. Ericsson LM Tel. Co.*, 2008 WL 5170640, at *9 (S.D.N.Y. Dec. 10, 2008) ("expressions of confidence"); *Okla. Firefighters Pension & Ret. Sys. v. Xerox Corp.*, 300 F. Supp. 3d 551, 570 (S.D.N.Y. 2018), *aff'd sub nom. Arkansas Pub. Employees Ret. Sys. v. Xerox Corp.*, 2019 WL 2394302 (2d Cir. June 6, 2019) ("things are going well"); *In re Ferrellgas Partners, L.P., Sec. Litig.*, 2018 WL 2081859, at *5 (S.D.N.Y. Mar. 30, 2018), *aff'd*, 764 F. App'x 127 (2d Cir. 2019) ("best-in-class"); *In re Xinhua Fin. Media, Ltd. Sec. Litig.*, 2009 WL 464934, at *8 (S.D.N.Y. Feb. 25, 2009) ("strong and experienced management").

[13] As at least one district court has observed, "Item 503 applies only to registration statements and prospectuses, thus making plaintiffs' reliance on this provision misplaced." *In re BHP Billiton Ltd. Sec. Litig.*, 276 F. Supp. 3d 65, 89 (S.D.N.Y. 2017).

2. Statements Regarding Japan Performance Were Not False Or Misleading

In addition to claiming, wrongly, that Defendants made false statements about IQOS clinical trials, Plaintiffs also claim that Defendants made false statements regarding IQOS sales in Japan by failing to disclose adverse sales trends that materialized by the end of the first quarter of 2018. *E.g.*, ¶¶ 275-302. This is a textbook example of "fraud by hindsight" pleading, *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000), and the CAC identifies no actionable false statements about the actual or projected performance of IQOS in Japan.

a. *Defendants' Statements Of Expectation Are Inactionable Forward-Looking Statements And/Or Opinions*

Plaintiffs challenge Defendants' forward-looking statements regarding the performance of IQOS in Japan in 2018, including Defendants' statements that they (i) "*expected* to further drive [ ] positive momentum" for IQOS, (ii) "*expect[ed]*" "demand for HeatSticks . . . to grow further in the first quarter," and (iii) "*anticipated*" demand for IQOS to "further increase" in Japan in the first quarter of 2018. ¶¶ 276-78, 285-86. *See In re Barrick Gold Corp. Sec. Litig.*, 341 F. Supp. 3d 358, 375 (S.D.N.Y. 2018) ("[T]he Second Circuit has acknowledged 'the common-sense proposition that words such as *'expect'* identify forward-looking statements.'"); *JBCHoldings NY, LLC v. Pakter*, 931 F. Supp. 2d 514, 532 (S.D.N.Y. 2013) (statements about "*anticipated* revenue [are] forward-looking statements"). Defendants' forward-looking statements are protected under the PSLRA for at least two independent reasons: (i) the CAC contains no particularized allegations that Defendants had "actual knowledge that [the statements were] false or misleading" and (ii) the statements were identified as forward looking and "accompanied by meaningful cautionary statements." 15 U.S.C. § 78u–5(c); *Aratana Therapeutics*, 315 F. Supp. 3d at 758.

First, Plaintiffs fail to meet the high bar of pleading actual knowledge of falsity, which "attaches only upon proof of knowing falsity." *CTPartners*, 173 F. Supp. 3d at 25. As described

in more detail below, § I.A.2.c, Plaintiffs simply repeat Defendants' April 2018 hindsight analysis for slower-than-expected IQOS growth in Japan through March 2018, without specifically alleging when and how Defendants knew—supposedly before the quarter ended—that (i) sales would lag expectations for the quarter; and (ii) the reasons for that lag. *See generally* ¶¶ 277-86. Nowhere does the CAC even attempt to plead—on the basis of even a single contemporaneous "document[], meeting[], or report[]"—that any facts undermining PMI's expectations for IQOS in Japan actually existed, let alone were known to Defendants, when they made the challenged statements of expectation in February 2018. *Goplen v. 51job, Inc.*, 453 F. Supp. 2d 759, 770-71 (S.D.N.Y. 2006) (plaintiffs failed to identify evidence showing "defendants knew or should have known that the fourth quarter revenue and earnings projections were misleading at the time of the [statements]"). This type of complaint—supported by speculation, but no facts—does not satisfy the heightened pleading requirements of Rule 9(b) and the PSLRA. *See CTPartners*, 173 F. Supp. 3d at 41 (Plaintiff's theory "fails to support a claim for securities fraud because, quite simply, it is complete conjecture."). As such, Plaintiffs' "self-serving speculation" about when adverse market trends emerged in Japan "falls far short of a plausible pleading, let alone one that satisfies Rule 9(b)." *Id*.

Second, Defendants identified their forward-looking statements as such and provided the market with meaningful cautionary language. *See, e.g.*, Ex. 3, 2017 10-K, at 6 (identifying statements using the words "expects," "anticipates," "projects" as forward-looking, cautioning that PMI "cannot guarantee that any forward-looking statement will be realized" and "actual results could vary materially from those anticipated");[14] *id.* at 9 (warning investors that "[w]e may be unable to anticipate changes in consumer preference" like "convinc[ing] adult smokers to convert

[14] In its public statements, PMI explicitly incorporated its forward-looking statement warnings and cautionary language. *E.g.*, Ex. 22, Earnings Call Tr. (Apr. 19, 2018), at 3; Ex. 9, CAGNY Pres., at 2; *Biovail*, 615 F. Supp. 2d at 233 (incorporation by reference satisfies PSLRA safe harbor).

to our RRPs"); Ex. 5, Q1 2018 Earnings Pres., at 3 ("PMI's business risks include . . . intense competition" and "changes in adult smoker behavior[.]").

Defendants' projections and statements of expectation are also not actionable for the independent reason that they are statements of opinion. *See Sanofi*, 87 F. Supp. 3d at 531 ("expectations for the future" are opinions not "presently existing, objective facts"). Indeed, the CAC does not satisfy the *Omnicare* test for opinion liability because it (i) is devoid of any allegations that Defendants disbelieved their own projections or included false embedded facts in those projections; and (ii) fails to identify omitted facts that rendered Defendants' 2018 Japan projections misleading to a reasonable investor. *Omnicare*, 135 S. Ct. at 1322, 1327, 1332.[15]

b. *Defendants' Puffery Statements Regarding Japan Are Inactionable*

Plaintiffs also challenge Defendants' statements that (i) there was "*positive momentum*" and "*strong momentum*" behind IQOS, (ii) it was "begin[ning] 2018 in *excellent shape*," (iii) management viewed PMI as a "*growth stock*" because they believed that "8%-plus currency neutral net revenue growth is not just a 2017 or 2018 phenomenon," and their (iv) "*priority* is to go deeper with IQOS" in 2018. ¶¶ 276-77, 280-81, 287-88, 289-92. These statements of corporate optimism are not actionable because they do not supply any objective facts upon which a reasonable investor would rely. *See Frankfurt-Tr. Inv. Luxemburg AG v. United Techs. Corp.*, 336 F. Supp. 3d 196, 227 (S.D.N.Y. 2018) (statements were "non-actionable puffery because they conveyed no meaningful, objective data that an investor would rely upon");[16] *see also* App'x A.

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[15] Defendants' forward-looking statements also are protected by the bespeaks caution doctrine. *See, e.g.*, *Rombach*, 355 F.3d at 173.

[16] *Friedman v. Endo Int'l PLC*, 2018 WL 2021561, at *2 (S.D.N.Y. Apr. 27, 2018), *aff'd*, 2019 WL 1890764 (2d Cir. Apr. 29, 2019) ("maintain the magic"); *In re Bausch & Lomb, Inc. Sec. Litig.*, 592 F. Supp. 2d 323, 354 (W.D.N.Y. 2008) ("optimistic about our future growth"); *Wilbush v. Ambac Fin. Grp., Inc.*, 271 F. Supp. 3d 473, 494 (S.D.N.Y. 2017) ("primary goal"); *In re Nokia*

c. *Plaintiffs Fail To Plead Facts Establishing That Any Statement Of Current Or Historical Fact Was False When Made*

The CAC fails to allege particularized facts showing that any statement about IQOS' performance in Japan was false when made. *Gissin v. Endres*, 739 F. Supp. 2d 488, 501 (S.D.N.Y. 2010) ("complaint must 'state with particularity the specific facts in support of [plaintiffs'] belief that [defendants'] statements were false when made"). The CAC simply recites adverse market developments that became apparent in April 2018—when PMI disclosed them—and claim it was securities fraud for Defendants not to have disclosed them two months earlier. That is not securities fraud. *In re Express Scripts Holdings Co. Sec. Litig.*, 2019 WL 2004302, at *4 (2d Cir. May 7, 2019) (allegations that "defendants should have anticipated future events and made certain disclosures earlier than they actually did do not suffice to make out a claim of securities fraud").

First, Plaintiffs challenge Defendants' early February 2018 statements that (i) "[c]ontinued investment behind IQOS in 2018 is expected to further drive its positive momentum," (ii) 2017 inventory movements reflected "an increasing demand for HeatSticks, which [PMI] expected to grow further in the first quarter," (iii) PMI "beg[a]n 2018 in excellent shape," and (iv) the "supply of HeatSticks [is] no longer an issue." ¶¶ 276-82. Plaintiffs claim the statements were false because Defendants failed to disclose that PMI allegedly (i) was "struggling" to "convert adult smokers" in Japan, (ii) had "saturated the younger [market]" in Japan, (iii) was "experiencing plateauing market share," and (iv) knew that "shipments of HeatSticks to Japan were on track to decline." ¶¶ 277, 279, 281. But those alleged omissions are nothing more than Mr. King's *hindsight* statements on the April 19, 2018 earnings call regarding why the first quarter Japan numbers came up short of expectations. Ex. 22, Earnings Call Tr. (Apr. 19, 2018), at 8. Plaintiffs'

Oyj (Nokia Corp.) Sec. Litig., 423 F. Supp. 2d 364, 398 (S.D.N.Y. 2006) ("continued momentum").

hindsight pleading technique cannot support a securities fraud claim. *See Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994).

Plaintiffs also speculate that demand for IQOS was "slowing as consumers learned of [the January 25, 2018 TPSAC] vote," and that Defendants somehow knew the alleged impact of the TPSAC vote in Japan less one month after the vote occurred. *See, e.g.*, ¶ 281. But they offer no particularized factual allegations to support this theory. Plaintiffs simply cite two newspaper articles that reported the TPSAC vote, ¶¶ 117-18, without alleging any facts about how or when that news supposedly translated to slowing growth in Japan. Further, IQOS continued to grow in Japan in the first quarter of 2018, after the TPSAC vote was reported, just not at the level that Defendants anticipated when they resolved the supply constraints. Ex. 22, Earnings Call Tr. (Apr. 19, 2018), at 7, 13. And IQOS grew in other markets as well, which also undermines Plaintiffs' unsupported theory regarding the impact of the non-binding TPSAC vote. *Id.* at 6 ("we remain on track to double our worldwide in-market sales of heated tobacco units compared to 2017"). Finally, one of TPSAC's recommendations was that IQOS *does* reduce exposure to the HPHCs in cigarette smoke—a recommendation that was hardly likely to dampen interest in the product.

Second, Plaintiffs challenge Defendants' statements at the February 21, 2018 CAGNY conference, during which Defendants provided their views, based expressly on the available Japan data for the month of January. ¶¶ 287-98. None of those statements included a false or misleading fact. The statement that PMI was "a growth stock," ¶ 287-88, clearly is inactionable opinion and/or puffery, especially when read with the benefit of context that the CAC omits: "Today I *believe* we are exhibiting more of the *attributes* of a growth stock as well." Ex. 18, CAGNY Tr. (Feb. 21, 2018), at 12; *Omnicare*, 135 S. Ct. at 1322. Similarly, Plaintiffs assert it was false for Defendants to state at CAGNY that IQOS could "start[] enjoying word of mouth" in Japan and it was PMI's "priority to go deeper with IQOS in [the] existing launch markets" in 2018. ¶¶ 290, 292. Yet, the

CAC provides nothing beyond conclusory allegations regarding the extent to which Japanese consumers were communicating amongst each other about IQOS, or what Defendants' business priorities were for Japan in 2018. As such, there is no basis to conclude those statements were false when made. In fact, Defendants' reference to "launch markets" did not even relate specifically to Japan; it referred to *all* "*38 markets"* where IQOS was sold, Ex. 18, CAGNY Tr. (Feb. 21, 2018), at 9, and Plaintiffs offer no basis to conclude that PMI did not plan to "go deeper" in some or all of its IQOS markets.

Finally, the CAC points to Defendants' statements at CAGNY that (i) the IQOS market share "growth trend continued in January"; (ii) "weekly offtake shares in Japan continued to grow in January"; and (iii) there was "high IQOS switching across markets" (*i.e.*, switching from traditional cigarettes to RRPs). ¶¶ 293-98. Regarding market share growth, Plaintiffs challenge Defendants' statement that PMI had a 16.3% market share in Japan in January 2018, ¶ 135, and point to Mr. King's statement on the first quarter 2018 earnings call that the January figure—with the benefit of hindsight—was "probably a little overstated." ¶ 146. But that was not an acknowledgment that the January figure—which clearly was identified as an estimate based on available data—somehow was false. Ex. 9, CAGNY Pres. (Feb. 21, 2018), at 67. Instead, Mr. King explained that market share calculations depend on a comparison of market participants' inventory numbers, which are constantly in flux, and there is thus "always a bit of noise" in the monthly data (which is why PMI "focus[es] more on quarterly [numbers]"). Ex. 22, Earnings Call Tr. (Apr. 19, 2018), at 8. Inventory movements in late 2017 through early 2018 resulted in January market share calculations that were slightly above what the quarterly average turned out to be. *Id*.

There is nothing remarkable, much less actionable, about the fact that inventory movements resulted in adjustments to prior estimates. In fact, Plaintiffs omit that the market share numbers for Japan continued to rise throughout the first quarter of 2018, from 14.1% (at the close

of 2017) up to 15.8% at the end of the first quarter. *Id*. Plaintiffs do not dispute these facts, but allege that Defendants "made no mention of this [inventory movement] issue" at CAGNY. Here again, however, Plaintiffs do not allege any facts suggesting that Defendants should have—or even could have—predicted how its competitors' inventory movements or even PMI's own would change throughout the quarter. That is insufficient to state a claim. *See Foley v. Transocean Ltd*., 861 F. Supp. 2d 197, 208 (S.D.N.Y. 2012) ("Corporate officials need not be clairvoyant").

d. *Plaintiffs Do Not Adequately Allege A Violation Of Item 303 Or 503*

Plaintiffs allege in conclusory fashion that PMI violated Items 303 and 503 because it did not disclose the supposedly known risk posed by unfavorable trends in Japan—in particular that "the market for early adopters . . . reached saturation." ¶¶ 306-08. They are wrong. *First*, as described above, Plaintiffs have failed to allege that any adverse trends in Japan actually existed *and were known* by Defendants when they made the challenged disclosures in February 2018. That alone precludes an Item 303 claim. *Endo Int'l PLC*, 2019 WL 1890764, at *3 (trend or uncertainty must be "presently known to management"). *Second*, Defendants provided detailed warnings of the exact risks Plaintiffs highlight. *See, e.g.*, Ex. 3, 2017 10-K, at 8 ("We compete primarily on the basis of product quality . . . and, *increasingly, adult smoker willingness to convert to our RRPs*"), *id.* at 9 ("To be successful, we must . . . convince adult smokers to convert to our RRPs"). *See Chipotle*, 2017 WL 933108, at *17 (dismissing Item 303 and 503 claims where the alleged risk "was adequately described").

B. Plaintiffs Fail To Plead A Strong Inference Of Scienter

The CAC also fails for the independent reason that it does not come close to pleading a "strong inference" of scienter—*i.e.*, an "intent to deceive, manipulate, or defraud"—for any Defendant. 15 U.S.C. § 78u-4(b)(2); *Tellabs, Inc. v. Makor Issues & Rights, Ltd*., 551 U.S. 308, 319 (2007). To meet this standard, it is not sufficient to set out facts from which, if true, "a

reasonable person *could* infer that the defendant acted with the required intent." *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 110-11 (2d Cir. 2009) (emphasis in original). The "strong" inference must be "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. A strong inference of scienter may be supported by alleging particularized facts showing (i) that defendants had the "motive and opportunity to commit fraud"; or (ii) "strong circumstantial evidence of conscious misbehavior or recklessness." *ECA*, 553 F.3d at 198. The CAC fails to do either.

1. Plaintiffs' Motive Allegations Are Deficient

To satisfy the "motive and opportunity" test, a plaintiff must show that the defendant "benefitted in some concrete and personal way from the purported fraud." *Novak*, 216 F.3d at 307-08. Plaintiffs attempt to demonstrate "motive and opportunity" by asserting that one Individual Defendant—Mr. Calantzopoulos—sold 84,000 total shares in two separate transactions during the Class Period, over one year apart, for proceeds of $8.67 million. ¶¶ 316-20. But "[t]he mere fact that insider stock sales occurred does not suffice to establish scienter." *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009). Instead, Plaintiffs must demonstrate, at a minimum, that the sales are "unusual" or "suspicious" in timing or amounts. *See Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 54 (2d Cir. 1995); *Gildan Activewear*, 636 F. Supp. 2d at 270-71. Plaintiffs do not and cannot do so.

First, Plaintiffs omit basic allegations regarding Mr. Calantzopoulos's total holdings of PMI stock at the beginning and end of the Class Period, the percentage change in those holdings, or the profits derived from his sales. That facial pleading deficiency alone is enough to defeat Plaintiffs' motive-based theory of scienter, *see Tyler v. Liz Claiborne, Inc.*, 814 F. Supp. 2d 323, 335 (S.D.N.Y. 2011) (plaintiffs must allege "overall percentage changes in defendants' holdings"

and "profits" to establish scienter), and it cannot be cured. That is because the public record clearly demonstrates that Mr. Calantzopoulos followed consistent patterns of trading, did not make outsized trades during the Class Period, and his PMI shareholdings actually *increased* throughout the Class Period. Specifically, he sold 7-8% of his total non-deferred shares *every* February from 2015 through 2019, including the two Class Period sales Plaintiffs identify in 2017 and 2018. *See* Ex. 41, Calantzopoulos Form 4s; App'x B; *see also Gildan Activewear*, 636 F. Supp. 2d at 270-71 (sales of 22.5% not unusual). And far from "unloading" his PMI stock, ¶ 318, Mr. Calantzopoulos's non-deferred shareholdings *grew* by 20% over the course of the Class Period, from 508,384 to 610,435 shares. *See Bristol-Myers Squibb*, 312 F. Supp. 2d at 561 (increase in shareholdings is "wholly inconsistent with fraudulent intent").[17]

Second, the timing of Mr. Calantzopoulos's two Class Period sales is not sufficiently close to the disclosure of "bad news" to establish the requisite strong inference of scienter. *See Gildan Activewear*, 636 F. Supp. at 271 ("Plaintiffs' allegations are empty vessels, as the trades occurred weeks before the principal allegation of material misstatement, and many months before the release of any negative information"); *In re Sina Corp. Sec. Litig.*, 2006 WL 2742048, at *12 (S.D.N.Y. Sept. 26, 2006) (finding "no inference of scienter because [ ] the sales occurred more than a month before" a corrective disclosure). The first "revelation of the alleged falsity" was the *Reuters* Article in late December 2017. Yet, the first trade occurred on February 15, 2017, more than 10 months earlier. ¶¶ 316, 323. The second trade, on February 22, 2018, occurred *after* the TPSAC vote, and two months prior to the April 2018 earnings announcement. ¶¶ 316, 325-30. The timing of Mr. Calantzopoulos's trades, and the amounts sold relative to the amounts retained

[17] The lack of allegations regarding sales by the other Individual Defendants further shows lack of intent. *See Acito*, 47 F.3d at 54 ("fact that the other defendants did not sell their shares during the relevant class period undermines" inference of scienter).

do not fit the paradigm of an executive fraudulently divesting himself of shares on the eve of bad news hitting the market. *See Frazier v. VitalWorks, Inc*., 341 F. Supp. 2d 142, 161-62 (D. Conn. 2004) (nine- and seven-week gaps between sales and bad news did not raise a "strong inference that defendants were trying to sell off stock on the basis of inside information").

Third, Plaintiffs' attempt to bolster their motive allegations by citing stock sales made by two non-defendants—General Counsel Marc Firestone and Board Chairman Louis C. Camilleri—also fails. ¶ 316. Notably, Messrs. Firestone and Camilleri are mentioned nowhere else in the CAC, and are not alleged to have made any false statements or to have known of the alleged falsity of public statements made by others at PMI. By failing to allege any nexus between these two non-defendants and the alleged fraud, Plaintiffs' reliance on their routine stock transactions fails to establish any inference, let alone a strong inference, of scienter.[18] *See Alaska Laborer Employers Ret. Fund v. Scholastic Corp.*, 2010 WL 3910211, at *7 (S.D.N.Y. Sept. 30, 2010) (stock sales by non-defendant insiders insufficient to establish scienter where plaintiff "allege[d] no statements or conduct attributable to the non-defendant purchasers").

Finally, Plaintiffs' illogical theory that Defendants were engaged in a fraud on PMI's investors is undermined by the fact that senior management at PMI—including Mr. Calantzopoulos, Mr. Firestone, and Mr. Camilleri—retained substantial holdings of PMI stock and, in the case of Mr. Calantzopoulos and Mr. Firestone, their non-deferred shareholdings

[18] There was nothing "unusual" or "suspicious" about the non-defendants' stock sales. Mr. Firestone sold 13% and 9% of his total non-deferred shares in two separate sales during the Class Period; he sold 17% of his total non-deferred shares two months *before* the Class Period; and he retained 135,439 non-deferred shares at the end of the Class Period. *See* Ex. 42, Firestone Form 4s; App'x C. Mr. Camilleri sold 8% and 15% of his total non-deferred shares in two separate sales during the Class Period; he made several comparable transactions from 2014 through 2019, including two sales of 32% and 16% of his total non-deferred shares *before* the ones identified in the CAC; he sold a significant number of shares one month *after* the third alleged corrective disclosure; and he retained 615,495 non-deferred shares at the end of the Class Period. *See* Ex. 43, Camilleri Form 4s; App'x D.

increased by the end of the Class Period. Exs. 41-45, Form 4s; App'x B, C, E; *see also Avon Pension Fund v. GlaxoSmithKline PLC*, 343 F. App'x 671, 673 (2d Cir. 2009) (increases and retention of stock "cannot support a 'cogent and compelling' inference of fraudulent intent").

2. Plaintiffs' Recklessness Allegations Also Fail

Because Plaintiffs fail to allege a cognizable motive, their allegations of recklessness must be "correspondingly greater." *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001). "Recklessness," in this context, is "not merely a heightened form of negligence," but must be "conscious . . . *i.e.*, a state of mind approximating actual intent." *S. Cherry St.*, 573 F.3d at 109. Plaintiffs do not meet this standard.

a. *No Recklessness Regarding IQOS Clinical Studies*

Plaintiffs principally rely on allegations made by two former employees and statements that *Reuters* attributed to third parties as support for their contention that Defendants "knew, or recklessly disregarded" that "studies used to support their claim that IQOS is less harmful than cigarettes were not conducted in accordance with GCP and did not support their false claims." ¶¶ 62-86, 309. Those allegations do not show that the "individual defendants *actually possessed* the knowledge highlighting the falsity of public statements" at the time such statements were made. *Hensley v. IEC Elecs. Corp.*, 2014 WL 4473373, at *5 n.1 (S.D.N.Y. Sept. 11, 2014). Moreover, the FDA's decision, made with the benefit of all of PMI's data and hundreds of public comments, as well as the *Reuters* findings, to authorize the sale of IQOS as "appropriate for the protection of public health" belies the allegation that the studies did not follow GCP or support PMI's claims.

Plaintiffs rely heavily on allegations by Tamara Koval, a former "Company scientist," who was terminated from PMI in January 2015—over 18 months before the start of the Class Period, and almost two years prior to PMI's submission of its IQOS marketing authorization application to the FDA. ¶¶ 62, 81. But the bulk of Ms. Koval's allegations merely reflect her disagreements

with aspects of PMI's clinical program, the details and results of which were disclosed to the FDA in a *public* application process. ¶¶ 62-84. The fact that Ms. Koval harbored such disagreements in no way reveals fraudulent intent on the part of the Individual Defendants. *See Harris v. AmTrust Fin. Servs., Inc*., 135 F. Supp. 3d 155, 171 (S.D.N.Y. 2015), *aff'd*, 649 F. App'x 7 (2d Cir. 2016) ("disagreement with management's choices" did not support fraud); *In re Magnum Hunter Res. Corp. Sec. Litig.*, 26 F. Supp. 3d 278, 295 (S.D.N.Y. 2014), *aff'd*, 616 F. App'x 442 (2d Cir. 2015) ("litany of criticisms of accounting practices" by confidential witnesses did not support inference of fraud).

Moreover, Ms. Koval is not alleged to have had a single conversation or other interaction with five of the six Individual Defendants regarding the IQOS clinical studies. The CAC alleges only that on a single occasion in 2014 Ms. Koval communicated to Dr. Picavet her purported concerns about the collection of unusually large urine samples in a clinical study in Poland. *See* ¶ 81. Ms. Koval admittedly lacks knowledge regarding how her concerns were addressed,[19] but *Reuters* acknowledged that the principal investigator in charge of the Poland study marked such samples as "adverse events" following discussion with PMI, and that the matter was reported to the FDA, which is not alleged to have (and indeed has not) taken issue with PMI's clinical processes or methodologies. Ex. 12, *Reuters* Article, at 15; *see also* Ex. 26, PMI Scientific Update (Dec. 2017), at 5 (noting that PMI requested the CRO perform an audit and document the adverse events). In any event, Ms. Koval's conversation with Dr. Picavet about the Polish study in no way supports an inference that Dr. Picavet acted with fraudulent intent when characterizing PMI's clinical studies and summarizing their results. ¶¶ 167-68, 179-86, 225-29, 255-61; *S. Cherry St*., 573 F.3d at 109.

[19] That alone undercuts Ms. Koval's Poland study allegation. *See Frankfurt-Tr. Inv. Luxemburg AG*, 336 F. Supp. 3d at 222, 228.

Apart from Ms. Koval, Plaintiffs cite to statements allegedly made by third-party contractors to *Reuters* regarding certain IQOS clinical trials, ¶ 65, and obliquely reference one former employee's beliefs on when certain IQOS study results were made available to PMI, ¶ 86. None of these purported witnesses is alleged to have interacted with *any* Individual Defendant or to have any information about what any Individual Defendant knew when making the statements Plaintiffs now claim were false. Because these witnesses did not have "any contact with the Individual Defendants," the law "is abundantly clear that [their] allegations are insufficient to support scienter." *Wilbush v. Ambac Fin. Grp., Inc*., 271 F. Supp. 3d 473, 497 (S.D.N.Y. 2017).[20]

Lastly, it is well settled that Plaintiffs' speculative and conclusory allegation that the Individual Defendants, because of their senior positions at PMI, "would have been" aware of information that purportedly contradicted their public statements, *see* ¶¶ 310-14, does not support a strong inference of scienter, *see Plumbers & Steamfitters Local 773 Pension Fund v. Canadian Imperial Bank of Commerce*, 694 F. Supp. 2d 287, 300 (S.D.N.Y. 2010) ("[A]ccusations founded on nothing more than a defendant's corporate position are entitled to no weight.").[21]

b. *No Recklessness Regarding Japan Projections*

Plaintiffs' recklessness allegations regarding PMI's Japan projections fare no better. ¶ 309. The CAC does not cite a single piece of evidence suggesting that any Defendant intended to deceive shareholders, much less had "knowledge" that any projections they made were "false." *Id.* Instead, the thrust of Plaintiffs' allegations is that PMI's April 19, 2018 announcement of slower-than-expected growth in Japan deviated from projections and estimates made months

[20] *Local No. 38 Int'l Bhd. of Elec. Workers v. Am. Express Co.*, 724 F. Supp. 2d 447, 460 (S.D.N.Y. 2010) (no scienter where CWs "had no contact" with defendants); *Glaser v. The9, Ltd*., 772 F. Supp. 2d 573, 589-90 (S.D.N.Y. 2011) (witness was not "privy to [defendants'] knowledge").

[21] *See Ferrellgas Partners*, 2018 WL 2081859, at *19 (Plaintiffs must show "specific instances in which Defendants received information that was contrary to their public declarations.").

beforehand. ¶¶ 139-54. In other words, Plaintiffs ask the Court to presume—with no underlying factual allegations to support the presumption—that something known in April 2018 necessarily was known months earlier, and should have been disclosed at that time. That is plainly insufficient. *See Acito*, 47 F.3d at 53 ("Mere allegations that statements in one report should have been made in earlier reports do not make out a claim of securities fraud."). By failing entirely to allege any particularized facts demonstrating that "current data" contradicted statements made by Defendants at the time their statements were made, Plaintiffs' claim fails. *See Shields*, 25 F.3d at 1129-30.

Plaintiffs' allegations related to Defendants' projections for IQOS in Japan boil down to a generalized assertion of "fraud by hindsight," which courts have rejected time and again. *See, e.g.*, *Waterford Twp. Police & Fire Ret. Sys. v. Reg'l Mgmt. Corp.*, 723 F. App'x 20, 22 (2d Cir. 2018) (rejecting plaintiff's allegations regarding optimistic projections on this basis); *Shields*, 25 F.3d at 1129 ("technique" of pointing to "statements by defendants predicting a prosperous future and hold[ing] them up against the backdrop of what actually transpired. . . . *is not a cause of action, and does not support an inference of fraud*").

c. *Plaintiffs' "Core Operations" Theory Fails*

Plaintiffs next resort to the dubious "core operations" doctrine, *see* ¶ 315, which is at best a "supplementary but not independently sufficient" means to plead scienter. *See Cortina v. Anavex Life Scis. Corp.*, 2016 WL 7480415, at *7 (S.D.N.Y. Dec. 29, 2016) ("[T]here is considerable doubt whether the core operations doctrine survived enactment of the PSLRA, and many courts have held that it is no longer valid."). In any event, it does not apply here, as sales of IQOS amounted to only approximately 0.9% to 4.9% of the Company's net revenue during the relevant period. *See* Ex. 3, 2017 10-K, at 23-24. Such a small component of PMI's business cannot constitute a "core" operation, such that any and all Company executives can be imbued with knowledge of all day-to-day developments. *In re Federated Dep't Stores, Inc. Sec. Litig.*, 2004

WL 444559, at *5 (S.D.N.Y. Mar. 11, 2004) (subsidiary comprising 10% of a company's assets was not a "core operation"). Indeed, "courts have required that the operation in question constitute *nearly all of a company's business* before finding scienter based on the 'core operations doctrine,'" *Liz Claiborne, Inc.*, 814 F. Supp. 2d at 343, which clearly does not apply here.[22]

d. *The Non-Fraudulent Inference Is More Compelling*

When "determining whether the pleaded facts give rise to a 'strong' inference of scienter, the Court must take into account plausible opposing inferences." *Tellabs*, 551 U.S. at 323. Here, the most plausible inference—indeed, the only logical inference—is that Defendants believed in good faith that PMI conducted appropriate clinical studies showing that IQOS had the potential to be a better option than cigarettes, which the FDA now has validated, and that the success of IQOS in Japan would continue in 2018. This inference is supported by the following undisputed facts, among others: (i) Defendants disclosed, and did not conceal, the IQOS clinical methodology and results, and they repeatedly invested in and stated their belief in IQOS as a replacement for cigarettes; (ii) consistent with their publicly stated expectations of growth in Japan, PMI made significant operational changes to ship (and did ship) additional inventory to Japan, Ex. 3, 2017 10-K, at 24; (iii) Defendants maintained large holdings of PMI stock during the Class Period, and in some cases increased those holdings; and (iv) Defendants proactively disclosed the slower-than-expected IQOS growth in Japan, before it impacted PMI's financial performance. *See GlaxoSmithKline*, 343 F. App'x at 674 ("disclosure of [contradictory] meta-analyses results to the FDA and its publication of this information on its website effectively refutes plaintiffs' claim" of fraud).

[22] Because Plaintiffs fail to plead scienter for any individual at PMI, they fail to plead corporate scienter. *Friedman v. Endo Int'l PLC*, 2018 WL 446189, at *4 (S.D.N.Y. Jan. 16, 2018), *aff'd sub nom. Steamfitters' Indus. Pension Fund v. Endo Int'l PLC*, 2019 WL 1890764 (2d Cir. Apr. 29, 2019).

II. PLAINTIFFS FAIL TO PLEAD A SECTION 20(A) CLAIM

The Section 20(a) claim fails because the CAC (i) does not state a predicate Section 10(b) violation; and (ii) does not allege culpable participation by any Defendant. *Special Situations Fund III QP, L.P. v. Deloitte Touche Tohmatsu CPA, Ltd.*, 33 F. Supp. 3d 401, 437-39 (S.D.N.Y. 2014).

CONCLUSION

The CAC states no claim under the stringent pleading requirements of Rule 9(b) and the PSLRA. It should be dismissed with prejudice.

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Respectfully submitted,

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